K061951

510(k) Summary

Submitter: Frank B. Freedman, Ph.D.
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Contact Person:

Primary Contact	Secondary Contact
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Possis Medical, Inc.	Possis Medical, Inc.

Device Common Name: Thrombectomy Catheter

Device Trade Name: XPEEDIOR Rheolytic Thrombectomy Catheter

Device Classification Name: Embolectomy Catheter

Predicate Devices: AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter (K993564, K040013 and K052256) and other thrombectomy catheters

Device Description
When used with the AngioJet System, the Xpeedior Rheolytic Thrombectomy Catheter uses high velocity saline jets to percutaneously break-up and remove thrombus. These saline jets are contained within the Catheter and provide the suction that produces this effect.

Indications for Use
The AngioJet Xpeedior 120 Rheolytic Thrombectomy Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from infra-inguinal peripheral arteries $\geq$ 3.0 mm in diameter and upper extremity and infrainguinal lower extremity peripheral veins $\geq$ 3.0 mm in diameter.

Comparison to Predicate Devices
No design, packaging, sterilization or other device change was required to expand the AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter indications for use (K993564, K040013 and K052556).

Supporting Information
Applicable preclinical and clinical experience support the expanded indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2006

Possis Medical, Inc.
c/o Frank B. Freedman, Ph.D.
Senior Regulatory Affairs Associate
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K061951
AngioJet XPEEDIOR 120 Rheolytic Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II (Two)
Product Code: DXE
Dated: November 16, 2006
Received: November 17, 2006

Dear Mr. Freedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061951

Device Name: AngioJet Xpeedior 120 Rheolytic Thrombectomy Catheter

Indications For Use:

The AngioJet Xpeedior 120 Rheolytic Thrombectomy Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from infra-inguinal peripheral arteries 3.0 mm in diameter and upper extremity and infrainguinal lower extremity peripheral veins $\geq$ 3.0 mm in diameter.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061951